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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,347	10/28/2003	Shun-Por Li	MCP5007USCIP1	5595

27777 7590 04/02/2010

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1626	

NOTIFICATION DATE	DELIVERY MODE
04/02/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/695,347	LI ET AL.	
	Examiner	Art Unit	
	JASON M. NOLAN	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,17-23,32,34,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-7,32 and 36* is/are allowed.

6)☒ Claim(s) *8,17-23,34 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR § 1.114, including the fee set forth in 37 CFR § 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR § 1.114, and the fee set forth in 37 CFR § 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR § 1.114.

Applicant's submission filed on November 24, 2009 has been entered. As filed, Claims 1-8, 17-23, 32, 34, 36, & 37 are pending; of which, Claim 1 is currently amended. Claims 9-16, 24-31, 33, & 35 are cancelled.

Response to Amendment

Applicant's amendment with respect to Claim 1 has been fully considered and is entered. The amendment inserts the phrase "said overcoated shell portion surrounding said core" at the end of the first paragraph of the claim. After reconsideration, the Examiner has determined that said phrase, read in light of the specification, does not further limit the scope of invention (as compared to the previously submitted Claim 1) because the phrase is ambiguous.

The phrase is ambiguous because: 1) the phrase is not clearly indicative of whether the overcoated shell portion surrounding the core is "in direct contact with the core" or "in direct contact with the subcoating that substantially surrounds the core;" and 2) Applicants have not provided any guidance in their response to indicate their intended effect of said phrase on the scope of Claim 1.

The relative portion of the instant specification (p. 14, ll. 23-29) is shown below:

> The shell may be substantially unitary and continuous, or the shell may comprise multiple portions, e.g. a first shell portion and a second shell portion. In certain embodiments, at least one such shell portion comprises the composition of the invention. In certain embodiments the shell or shell portions are in direct contact with the core. In certain other embodiments, the shell or shell portions are in direct contact with a subcoating that substantially surrounds the core. In certain embodiments, the shell or a shell portion may comprise one ore more openings therein.

As indicated above, the invention contemplates one circumstance where the shell portion is in direct contact with the core, and a different circumstance where the shell portion is in contact with a subcoating, and the subcoating, not the shell portion, is in direct contact with the core.

The examples in the specification (pp. 23-27) seem to support an interpretation where the overcoated shell portion is in direct contact with the core. In Example 1, Step A, the core is prepared by mixing ibuprofen granules, croscarmellose sodium, and magnesium stearate in a blender, and subsequently compressed into a tablet. In Step B, the shell portion is prepared by mixing gellan gum, carrageenan, and hydroxypropyl methyl cellulose. It is noted that the active ingredient is absent from the shell portion. In Step C, the shell portion from Step B is applied to the tablet core from step A in a mold assembly. There is no indication that a sub-coating is added to the core before application of the shell portion.

However, without any indication of Applicant's intent, the Examiner is left guessing what the instant amendment is supposed to indicate. If the amendment were clear, then it would provide another limitation in the claim, but the Examiner cannot

resolve the amendment in light of the specification and cannot presume what Applicant's intention was when amending the claim. The Examiner is required to examine the claim given its broadest reasonable interpretation that is consistent with the specification. Therefore, with the ambiguity unresolved, the Examiner must consider prior art relevant to both interpretations of the phrase "substantially surrounds the core."

Response to Applicant's Request for Reconsideration

In the Office Action mailed June 24, 2009, Claims 1-8, 17-23, & 32-37 were rejected over Kim *et al.* (WO 99/20745) in view of Chen *et al*. (US 5,922,352) and Sangekar *et al*. (US 4,992,277).

Kim *et al*. discloses a formulation described as an enteric coated granule containing a lactic acid bacteria, which is coated with a water-miscible coating material (p. 4, 1st & 4th paragraph). The dosage form is prepared by coating the bacteria-containing seed with a water-miscible coating material and then further coating the first coated product with a second coating (p. 4, 2nd paragraph). Thus, the shell coating in Kim *et al*. surrounds a subcoating that surrounds the core. However, Kim *et al.* does not disclose a "compressed core." In this manner, the instant invention is distinguished from Kim *et al*. reference.

Chen *et al*. discloses a delayed releasing, compressed core within a controlled release dosage form (Col. 6, ll. 30-1; Claim 1). The tablet "does not have a rapid release core but is provided with a core having delayed release properties which contains an

enteric coated calcium blocker compound which is prepared by mixing the calcium channel blocker with an enteric polymer in an aqueous medium and dispersing that mixture onto a solid pharmaceutical diluent to form a granulation." (Col. 1, ll. 60-7). In this manner, the instant invention is distinguished from the Chen *et al.* reference.

Sangekar *et al*. discloses an immediate release formulation having a compressed core comprised of diltiazem and a coating, wherein the coating comprises a swellable hydrophilic polymer (abstract and col. 2, ll. 62-65). In this manner, the instant invention is distinguished from Sangekar *et al*.

However, the reference discloses information that is relevant to the instant invention, and said information is evidence as to what one of ordinary skill in the art would have known at the time of invention. Sangekar *et al*. discloses that hydrophilic polymers utilized in the art include hydroxypropyl methylcellulose, which can be used alone or in combination with other hydrocolloids such as guar gum. (Col. 3, ll. 1-7) The hydroxypropyl methylcellulose is commercially available in various grades under several trade names including METHOCEL E, METHOCEL F, and METHOCEL K. These commercially available products have viscosities in a 2% aqueous solution ranging from 3500 to 100,000 cps (mPas). (Col. 3, ll. 16-43) The example in col. 4 discloses the procedure used therein, and states that the hydroxypropylmethyl cellulose is granulated with the active ingredient, the granules are compressed into a tablet core, and the tablet core may be film or sugar coated.

In this case, Claims 1-8, 32, & 36 are drawn to a dosage formulation having the following limitations: 1) a delayed release shell composition comprising 40-95 weight

percent of a water soluble polymer, 5-25 weight percent of carrageenan, and 0.5-5 weight percent of gellan gum; and 2) a burst-releasing core comprised of a tablet or capsule.

In this case, Claims 17-23, 34, & 37 are drawn to a dosage formulation having the following limitations: 1) a delayed release shell composition comprised of 40-95 weight percent of a water soluble polymer, 5-40 weight percent of carrageenan, and 0.5-30 weight percent of a lubricant; and 2) a burst-releasing core comprised of a tablet or capsule.

In this case, the formulations contain compressed core in the form of a tablet or capsule. The specification distinguishes such cores (referred to as “a self-contained unitary object”) from cores comprised of a plurality of granules or particles (referred to as "flowable material"). *See* p. 11, ll. 4-18. The specification states: “wherein the core is prepared by compression, a dry blending (i.e. direct compression), or wet granulation process may be employed, as known in the art.” *See* p. 13, ll. 19-21.

With this background, the previous prior art rejection is reconsidered. Kim *et al.* does not disclose a compressed core; Chen *et al*. does not disclose a burst release compressed core; and Sangekar *et al*. does not discloses a delayed release coating formulation around a compressed core. The Examiner finds that the combination of these three references would not lead one of ordinary skill in the art to try and prepare a composition having delayed release properties in the shell composition in combination with a core that releases the active ingredient in a prompt manner. Therefore, the 103-

prior art rejection of Claims 1-8, 17-23, 32, 34, 36, & 37 is withdrawn in view of the 103-prior art rejection provided herein, having more relevant disclosures.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Obviousness under 35 U.S.C. § 103 is a question of law, but is based on underlying facts of each case. The Supreme Court stated that an invention may be found obvious if it would have been obvious to a person having ordinary skill to try a course of conduct:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

> In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

KSR International Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

Although a combination of relevant options in a particular art may be obvious to try, there are instances where an invention would not have been obvious to try:

1) When the inventor would have had to try all possibilities in a field unreduced by direction of the prior art. In other words, when "what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful" an invention would not have been obvious. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). This is another way to express the *KSR* prong requiring the field of search to be among a "finite number of identified" solutions. 550 U.S. at 421.

2) An invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution. A finding of obviousness would not obtain where "what was 'obvious to try' was to explore a technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *O'Farrell*, 853 F.2d at 903. This expresses the same idea as the *KSR* requirement that the identified solutions be "predictable." 550 U.S. at 421.

In the instant application, Claims 17-23, 34, & 37 are drawn to a dosage formulation having the following limitations: 1) a delayed release shell composition comprised of 40-95 weight percent of a water soluble polymer, 5-40 weight percent of

carrageenan, and 0.5-30 weight percent of a lubricant; and 2) a burst-releasing core comprised of a tablet or capsule.

Claims 17-23, 34, & 37 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jain *et al*. (US 2002/0012675 A1; published 01/31/2002; filed 06/22/1999) in view of Banker *et al*. Chapter 11 in The Theory and Practice of Industrial Pharmacy Lea & Febiger (pub.) Lachman *et al*. (ed.) 1986, pp. 293-345; J.C. Carter *Pharmaceutical Canada* 2001, *1(3)*; Yamamoto *et al*. (US 5,756,123), and Sangekar *et al*. (US 4,992,277).

1. Determining the scope and contents of the prior art – Banker *et al*. discloses that delayed-action tablets were well known in the art at the time of the instant invention: "The delayed-action tablet dosage form is intended to release a drug after some time delay, or after the tablet has passed through one part of the GI tract into another. The enteric coated tablet is the most common example of a delayed-action tablet." (p. 331). Further, "[t]he coatings that are used today to produce enteric effects are primarily mixed acid functionality and acid ester functionality synthetic or modified natural polymers. . . Enteric coatings are employed for a number of therapeutic, safety, and medical reasons. . . Yet another reason for enteric coating may be the desire to release the drug undiluted and in the highest concentration possible within the intestine." (p. 332).

In other words, Banker *et al*. discloses that delayed release coatings have been utilized for some time (published in 1986). Banker *et al*. discloses that a "burst release"

of the active pharmaceutical may be desirable in some situations. Jain *et al*., *infra*, provides insight as per what polymers were useful for delayed release formulation.

Jain *et al*. discloses the typical polymers utilized in the art at the time the instant application was invented for controlled release applications. Controlled release includes delayed release profiles. *See* p. 1, [0002]. The polymers that one of ordinary skill in the art would look to are on p. 5, [0055] & [0056], shown below:

2. Rate-controlling Polymers

[0055] The present invention identifies pharmaceutically acceptable rate-controlling polymers (also referred to herein as rate controlling polymer material) that unexpectedly provide excellent controlled release properties for nanoparticulate compositions. Rate-controlling polymers include hydrophilic polymers, hydrophobic polymers, and mixtures of hydrophobic and hydrophilic polymers that are capable of retarding the release of a drug compound from a composition or dosage form of the present invention.

[0056] Particularly useful rate-controlling polymers for causing an effective controlled release of administered drug or agent following administration include plant exudates (gum arabic), seaweed extracts (agar), plant seed gums or mucilages (guar gum), cereal gums (starches), fermentation gums (dextran), animal products (gelatin), hydroxyalkyl celluloses such as hydroxypropyl cellulose (HPC), hydroxyethyl cellulose (HEC), hydroxypropyl methylcelluose (HPMC), and sodium carboxymethylcellulose (CMC), guar, pectin, and carrageenan. Additional polymers include poly(ethylene) oxide, alkyl cellulose such as ethyl cellulose and methyl cellulose, carboxymethyl cellulose, hydrophilic cellulose derivatives, polyethylene glycol, polyvinylpyrrolidone, cellulose acetate, cellulose acetate butyrate, cellulose acetate phthalate, cellulose acetate trimellitate, polyvinyl acetate phthalate, hydroxypropylmethyl cellulose phthalate, hydroxypropylmethyl cellulose acetate succinate, polyvinyl acetaldiethylamino acetate, poly(alkylmethacrylate) and poly(vinyl acetate). Other suitable hydrophobic polymers include polymers and/or copolymers derived from acrylic or methacrylic acid and their respective esters, waxes, shellac, and hydrogenated vegetable oils. Two or more rate-controlling polymers can be used in combination. The polymers are commercially available and/or can be prepared by techniques known in the art.

4. Quantities of Nanoparticulate Composition and Rate-controlling Polymer(s)

[0064] The relative amount of nanoparticulate agent in the controlled release compositions of the invention can vary widely and can depend upon, for example, the agent selected for controlled release delivery. The poorly soluble drug or pharmaceutically acceptable salt thereof may be present in any amount which is sufficient to elicit a therapeutic effect and, where applicable, may be present either substantially in the form of one optically pure enantiomer or as a mixture, racemic or otherwise, of enantiomers. The amount of poorly soluble drug compound, or pharmaceutically acceptable salt thereof, in the controlled release composition of the present invention is suitably in the range of from about 1 μg to about 800 mg, preferably in the range of from about 0.25 mg to about 600 mg and more preferably in the range of from about 1 mg to about 500 mg.

[0065] The nanoparticulate agent, preferably in combination with the surface stabilizer, can be present in the controlled release compositions of the invention in an amount of about 95% to about 5%, preferably about 80% to about 10% by weight based on the total weight of the dry composition.

[0066] The one or more rate-controlling polymers can be present in an amount of about 5% to about 95%, preferably about 10% to about 65% by weight based on the total weight

As shown above, hydroxypropyl cellulose, hydroxypropyl methylcellulose, and carrageenan were all known in the art to be useful for delayed release formulations. Jain *et al*. discloses that two or more rate-controlling polymers may be used in

combination and that the polymers are commerically available and/or can be prepared by techniques known in the art. Jain *et al*. further discloses the amount of polymer typically used in controlled release tablets (5-95%, preferably 10-65%, p. 5, [0066]). Jain *et al*. discloses that these compositions are preferably applied via spray drying. *See* pp. 6-7, [0075]-[0076].

Yamamoto *et al*. discloses "a composition comprising hydroxypropylmethyl cellulose (HPMC) as a water-soluble cellulose derivative base, carrageenan as a gelling agent, and a potassium ion as a co-gelling agent wherein the shapability of the HPMC is improved by blending carrageenan as a gelling agent and gelling this carrageenan with the co-gelling agent . . ." *See* col. 2, ll. 43-53. Yamamoto *et al*. further discloses preferred compositions, wherein the HPMC viscosity as a 2% aqueous solution is controlled, the amount of gelling and co-gelling agents needed, and how to apply this composition to a tablet. *See* col. 3-6.

Sangekar *et al*. discloses that hydrophilic polymers utilized in the art include hydroxypropyl methylcellulose, which can be used alone or in combination with other hydrocolloids such as guar gum. (Col. 3, ll. 1-7) The hydroxypropyl methylcellulose is commercially available in various grades under several trade names including METHOCEL E, METHOCEL F, and METHOCEL K. These commercially available products have viscosities in a 2% aqueous solution ranging from 3500 to 100,000 cps (mPas). (Col. 3, ll. 16-43)

Carter discloses that lubricants are agents added in small quantities to tablet and capsule formulations to improve certain processing characteristics. Carter discloses

that there are two major types of lubricants: hydrophilic, which are generally poor lubricants; and, hydrophobic, which are widely used, generally effective at relatively low concentrations, and may have anti-adherent and glidant properties. Most tableting materials require lubrication to some degree. Only a few drugs and excipients do not require lubrication; i.e., microcrystalline cellulose (these are the exception to the rule). In other words, it would be unexpected if a tablet or capsule did not contain a lubricant.

2. *Ascertaining the differences between the prior art and the claims at issue* – Yamamoto *et al*. discloses the combination of HPMC, carrageenan, and potassium ions as a preferred composition for coating tablets; however, the composition was designed as to be applied by dipping the tablet into the composition. The instant invention is drawn to a spray drying application; therefore, the composition would require a different viscosity from that in Yamamoto *et al*. Sangekar *et al*. discloses that various grades of hydroxypropyl methylcellulose are commercially available, wherein each grade has a specific viscosity. Jain *et al*. discloses compositions comprised of hydroxypropyl cellulose, hydroxypropyl methylcellulose, and carrageenan were known in the art to be useful for delayed release formulations are preferably applied via spray drying. Carter discloses that lubricants are generally found in all tablets and capsules. Thus, there are differences between each prior art reference and the instant application; however, taken as a whole the prior art discloses the limitations of the instant invention.

3. *Resolving the level of ordinary skill in the pertinent art* – the level of ordinary skill in the art may be found by inquiring into: (1) the type of problems encountered in the art; (2) prior art solutions to those problems; (3) the rapidity with which innovations

are made; (4) the sophistication of the technology; and (5) the education level of active workers in the field. *Custom Accessories, Inc.*, 807 F.2d at 962. All of those factors may not be present in every case, and one or more of them may predominate. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed.Cir.1983).

Based on the typical education level of active workers in pharmaceutical art, as well as the high degree of sophistication required to solve problems encountered in the art, the Examiner finds that a person of ordinary skill in the art would have at least a college degree in chemistry, biology, biochemistry, pharmacology, etc. and at least four years of work experience, i.e. a masters or doctorate level scientist.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness – none.

Conclusion – the Federal Circuit stated "[o]bviousness does not require absolute predictability of success . . . all that is required is a reasonable expectation of success." *In re O'Farrell* at 903-904. *In this case*, the prior art cited above supports the conclusion that a person of ordinary skill in the art, at the time of invention, would have been motivated to try known options within their technical grasp in the formulation art.

The known options include: the selection of polymers useful in a delayed release composition; the blending of polymers with gelling agents to control the viscosity of the composition; the application of the composition to the tablet or capsule via spray drying; and the use of a lubricant in said compositions.

Banker *et al*. teaches that a burst release of active ingredient is sometimes desirable for generating a high concentration of drug at a preferred time. The length of

time is controlled by the formulation composition and Jain *et al*. discloses the typical polymers utilized in the art for controlled release applications. Yamamoto *et al*. discloses that HPMC, carrageenan, and an inorganic cation are a desirable combination for a formulation composition.

The Examiner finds that the references are not vague, but in fact provide for a specific formulation encompassed within the instant claims. The references suggest that a combination of their features would likely be successful, including specific excipients and proportions thereof. One of ordinary skill in the art would have recognized that the delayed release may be controlled by varying the concentrations of the polymers and/or increasing the layer thickness. Therefore, the differences between the prior art and instant application compositions, with respect to viscosity and application technique would be adjustable in a predictable manner.

The Examiner finds that the references and prior art as a whole disclose a finite number of predictable solutions for a skilled artisan attempting to provide a delayed release formulation of an active pharmaceutical ingredient in the form of a tablet or capsule. Because the specification fails to produce evidence of unexpected results, a long-felt industrial need, or other secondary considerations, the Examiner concludes that one of ordinary skill in the art would have been motivated to arrive at the instant claimed invention with an expectation of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 & 23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" is a relative term which renders the claim indefinite due to its inherent ambiguity. Claims 8 & 23 are drawn to a limitation wherein the solid shell portion “is substantially free of pores having a diameter of 0.5 to 5.0 microns.” The term “substantially” suggests the shell portion may have pores within that range as long as there are not too many. How many pores are too many? In other words, if one tablet has a shell portion with only 1 pore of 5.0 microns, and another tablet has a shell portion with 10 pores of 5.0 microns, then which tablet is substantially free of the pores?

Said term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The examiner suggests deletion of said term.

Conclusion

The prior art references herein do not disclose or suggest the use of gellan gum in the shell portion composition. For this reason, Claims 1-7, 32, & 36 are allowed.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason M. Nolan whose telephone number is (571) 272-4356 and e-mail is Jason.Nolan@uspto.gov. The examiner can normally be reached Monday - Friday (9:00AM - 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M^{c}Kane, may be contacted at Joseph.McKane@uspto.gov or (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system, (Private PAIR or Public PAIR). Status information for unpublished applications is available through Private PAIR only. For information about the PAIR system, see http://pair-direct.uspto.gov. For questions on Private PAIR system, contact the Electronic Business Center at (866) 217-9197.

/Jason M. Nolan/

Examiner, Art Unit 1626